DEMOCRACY FORWARD FOUNDATION

January 28, 2021

Hon. Paul W. Grimm
United States District Judge
6500 Cherrywood Lane
Greenbelt, MD 20770

**RE: American Academy of Pediatrics, et al., v. FDA (No. 8:18-cv-883-PWG)**

Dear Judge Grimm:

Pursuant to the Court's January 19, 2022 Paperless Order, Plaintiffs submit this reply in support of their letter motion to amend this Court's July 12, 2019 Remedial Order, Doc. No. 127, pursuant to Rule 60(b)(5). A redline proposing an amendment to the Remedial Order is attached.

In its December 13, 2021 response, Doc. No. 197 ("FDA's Response"), FDA does not dispute that the Court has the power to grant Plaintiffs' request and order status reports. Nor does it deny that factual conditions have changed since the Court denied Plaintiffs' original request for status reports in the Remedial Order, or that Plaintiffs' limited request for information is suitably tailored to those changed conditions. Instead, FDA's sole argument is that "regular status reports are not warranted at this time." FDA's Response at 1. Thus, the sole question before the Court is an equitable one: would modification "protect the purpose" of the judgment in this case? *Duvall v Hogan*, No. ELH-94-2541, 2021 WL 2042295, at *16 (D. Md. May 21, 2021).

For the reasons stated in their letter motion, Plaintiffs respectfully submit that it would. Every one of the popular products with significant youth usage that was on the market before the September 9, 2021 deadline is still on the market today, despite none of them having received the marketing order required by the Family Smoking Prevention and Tobacco Control Act.[1] This reality undercuts the core purpose of the Court's judgment "by allowing unapproved tobacco products to be manufactured, advertised, and sold for five years or longer." Mem. Op., Doc. No. 73, at 44 (May 15, 2019) ("Merits Opinion").

FDA argues that Plaintiffs' request "boil[s] down to disagreements about how the agency should prioritize [its] limited resources." FDA's Response at 3. That is not the case. The requested relief would not interfere with FDA's prioritization or enforcement decisions at all. It would simply require FDA to provide information regarding when it expects to complete its mandatory duties under the Tobacco Control Act with regard to these large violators. That information would confirm how soon FDA will bring to a close the regulatory holiday that the

[1] Since filing their letter motion, Plaintiffs have continued to document the widespread post-deadline availability of the flavored e-cigarette products that have proven so appealing to young people, including unauthorized menthol-flavored products marketed by several of the largest manufacturers. *See An E-Cigarette Market Update*, Campaign for Tobacco-Free Kids (Dec. 2021), https://bit.ly/3tYwvUQ (last visited Jan. 25, 2022).

Court's orders sought to end, while leaving FDA free to prioritize its resources however it sees fit.

Indeed, Plaintiffs' request does not even conflict with FDA's stated priorities. In its response, FDA notes that it spelled out its "structured review process" in a February 2021 document. FDA's Response at 1-2 (citing FDA, *Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline* (Feb. 16, 2021), https://bit.ly/2WIq2za ("*Feb. 16, 2021 Perspective*")). In that explanation, the Director of FDA's Center for Tobacco Products, Mitch Zeller, explained that FDA intended to "dedicate a portion of its resources to reviewing the products that account for most of the current market." *Feb. 16, 2021 Perspective*. His explanation is worth quoting at length:

> *The continued marketing of these products has the potential to have the greatest public health impact—either positively or negatively—as they hold the largest overall market share and therefore likely used by the largest number of people.* For this reason, FDA pulled several applications into a separate review queue and dedicated resources to their review. By identifying and ensuring first review of these applications, we believe we can achieve the greatest public health impact most quickly. If FDA finds that a widely-used, currently marketed product does not meet the standard in the law for marketing, the Agency will not grant a marketing order and the product must be removed from the market. Conversely, if FDA finds that a widely-used, currently marketed product does meet the standard in the law for marketing, the Agency will grant a marketing order and the product may remain on the market subject to the conditions in the order. *In either case, earlier review ensures a faster transition to a marketplace of products that have been scientifically reviewed for their impact on public health.*

*Id.* (emphasis added). This is precisely what Plaintiffs explained in their letter motion: until the FDA completes its review of the products with the greatest market share, "[t]he e-cigarette products with the greatest public health impact—both overall and among kids—remain on the market for an indeterminate amount of time, despite receiving no FDA authorization." Pls.' Letter Mot., Doc. No. 195, at 3. While FDA may be free to change its priorities, it does not claim to have done so. Thus, all the status reports will require is that FDA disclose when it will accomplish the task that *FDA itself* prioritized.

FDA also points to the many challenges that tobacco product manufacturers have filed against some of the marketing denial orders it has issued to date. FDA's Response at 2-3. Plaintiffs support FDA's defense of those orders, and, to date, have filed eight *amicus curiae* briefs defending the agency's determinations. But with all due respect to FDA, those lawsuits are largely irrelevant to Plaintiffs' modification request here. The proposed status reports would not require FDA to alter its review of any applications or take any action that could subject it to additional lawsuits. They would simply confirm for the Court and Plaintiffs when we can expect the indefinite holiday enjoyed by the products with "the potential to have the greatest public health impact—either positively or negatively," *Feb. 16, 2021 Perspective*, to end.

Plaintiffs attach a proposal for amending the Remedial Order's decretal language. Prior to this submission, Plaintiffs conferred with FDA about the status report to determine what specific requirements would be feasible for FDA. FDA authorized Plaintiffs to say that, while it continues to believe status reports are not warranted at this time, it has no objection to paragraphs 6 and 7 of the proposed amended order if the Court does order relief. The parties were unable to agree on language for the third paragraph; Plaintiffs propose Option A, while FDA proposes Option B if the Court orders relief.

FDA's position is that the product-specific information described in Option A—both the estimates for deciding applications for particular products by specific dates and the detailed explanations for any revisions to those estimates—constitutes sensitive, potentially market-moving information and could contravene FDA's disclosure rules set forth in 21 C.F.R. § 1114.47.

Plaintiffs respond that 21 C.F.R. § 1114.47 applies only to information provided to FDA or communications between FDA and applicants; it does not prohibit FDA from disclosing estimates for when it will complete its own work, so long as the applicant has publicly acknowledged or authorized FDA to disclose the existence of its application. *See* 21 C.F.R. § 1114.47(b). Furthermore, because any estimated completion dates included in a status report will be publicly available, all investors will have the same information and there will be no risk of inequitable market activity. Finally, even if confidentiality concerns warranted withholding manufacturer-specific information, it would still be appropriate to require FDA to provide at least a general explanation if it revises its estimates downward in future status reports.

For the foregoing reasons and those in their opening letter motion, Plaintiffs respectfully request that the Court amend its Remedial Order to include paragraphs 6, 7, and 8 of the attached redline.

Respectfully Submitted,

*/s/ Jeffrey B. Dubner*
Jeffrey B. Dubner

*Counsel for Plaintiffs*